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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,276	HOLLENBECK ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *18-20 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/30/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 8/22/07 and IDS filed 7/30/07. Claims 1, 6, 7, 14 and 21 are amended. Claims 18-20 and 22 are withdrawn from examination. Claims 1-22 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1-17 and 21 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description.

Claims 1, 8 and 12 are directed to the use of polyelectrolyte in pharmaceutical compositions that contain drug-resin complex without identifying the ions associated with the polyelectrolyte. The specification does not describe the ions that may be associated with the polyelectrolyte. For example, Kupperblatt in US 5,882,677 at column 5, lines 34 and 35 disclose that polyelectrolyte having Hg or Ag ions would not be medically suitable. Therefore,

the use of any polyelectrolyte without identifying the ions associated with the polyelectrolyte in the claimed composition would not lead the artisan away from using polyelectrolytes having associated Hg or Ag ions and as such the disclosure is insufficient to meet the requirements for adequate written description under 35 USC 112, first paragraph.

Applicant may overcome this rejection by incorporating claims 8 and/or 12 into claim 1 and at the same time show that the ions associated with these polyelectrolytes are not Hg or Ag without the introduction of new matter into the claims or disclosure.

Claim 21 recites condition or symptoms. The specification fails to describe those "conditions" and "symptoms" treatable by the claimed composition of claim 1. The specification is thus insufficient to meet the requirements of 35 USC 112, first paragraph, written description.

Applicant may overcome this rejection by reciting the specific symptoms or conditions without the introduction of new matter into the claims or disclosure.

Response to Arguments

4. Applicant's arguments filed 8/22/07 have been fully considered but they are not persuasive.

Applicant argues that the amendment to claim stating that the polyelectrolyte is pharmaceutically acceptable would not lead one to use an electrolyte that is not pharmaceutically acceptable. Applicant also argues that amendment of claim 1 where categories of drug classes are recited provides description for the symptoms and conditions treatable by the various classes of drugs so that applicant believes that such recitation of classes of drugs in claim 21 overcomes the rejections relating to claim 21.

Response:

The recitation of pharmaceutically acceptable polyelectrolyte does not overcome the rejection because no specific polyelectrolyte is recited as being that and polyelectrolytes having Ag or Hg ions may also be pharmaceutical. A recitation of the polyelectrolyte used and the associated ions would overcome the rejection. Secondly, the recitation of the classes of drugs in claim 21 does not overcome the written description rejection for lacking description of treatable symptoms.

5. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Amended claim 21 recites that combination of drugs can be used. However, the specification as originally filed does not envision combination of drugs. Paragraphs [0035] and [0093] referred to by applicant as supporting the amendment to claim 21 do not disclose mixture or combination of drugs.

This rejection may be overcome by removing the new matter from amended claim 21.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 5, 6, 8, 13, 14 and 16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Cuna et al. ("Controlled-release liquid suspensions based on ion-exchange particles entrapped within acrylic microcapsule," in International Journal of Pharmaceutics 199 (2000), pp 151-158, provided by applicant on form PTO 1449).

Cuna discloses terbutaline-loaded ion-exchange resins where the resin is Dowex cation exchange resin of the H^+- form (abstract; paragraph 2.1-2.8) and EUDRAGIT polymer that meets the limitation of polyelectrolyte of claims 1 and 8; the dosage form contains hydroxypropylmethylcellulose meeting the limitations of claims 2 and 3 as the diffusion controlling membrane. Terbutaline is cation/positively charged in the resinate since the ion-exchange resin is a cation exchange resin. The presence of polysorbate meets the limitation of dispersion agent of claim 16 and the presence of the diffusible counter ions per liter of dispersion medium as claimed in claim 13 is inherent to the composition and the Dowex ion-exchange resin is a bead, thus meeting claim 14. Cuna anticipates the designated claims.

Response to Arguments

8. Applicant's arguments filed 8/22/07 have been fully considered but they are not persuasive.

Applicant argues that "Cuna fails to teach or suggest a liquid form controlled release drug composition" that includes "an electrolytic drug associated with an ion exchange resin and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug" because the Cuna's dispersion medium is a 0.75% hydroxymethylcellulose, which is a neutral polymer.

Response:

While Cuna disperses the EUDRAGIT microcapsules in hydroxypropylmethylcellulose as is stated by applicant according to Cuna at paragraph 2.7, page 154, Cuna initially suspends the drug-resin particles in solution of EUDRAGIT (paragraph 2.4) and it is the EUDRAGIT that is the polyelectrolyte, which meets the requirements of the polyelectrolyte of claims 1 and 8 as stated in the rejections. Therefore, Cuna teaches and suggests a liquid form controlled release drug composition" that includes "an electrolytic drug associated with an ion exchange resin and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug. The comprising language of the claims is open.

9. Claims 1-17 and 21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Nonomura et al. (US 4,894,239) provided by applicant on form PTO 1449, (also noted is EP-0 294 103 version of the Nonomura US patent submitted by applicant on 7/30/07).

Nonomura discloses sustained release resin microcapsule preparation comprising ion-exchange resin (abstract), which dosage form is produced as oral suspension (column 4, lines 55-62) meet the requirement for liquid formulation; the ion-exchange resin is either cationic (H+ form) or anionic (OH- form) either as DOWEX or Amberlite (column 2, lines 16-23) meeting claim 14; the Dowex or Amberlite resins are of the styrene-divinyl benzene type resins meeting claims 6 and 10; when the ion exchange resin is cationic, the drug in the complex is positively charged meeting claim 5 and when the exchanger is anionic, the drug is negatively charged meeting claim 9; the composition contains water permeable polymer coat formed of natural and non-natural polymers such as ethylcellulose, aminoalkyl methacrylate copolymer or the Eudragit polymer (column 3, lines 32-42) meeting claims 2-4; the composition or dosage form contains plasticizer or antioxidant such as BHA, BHT, tocopherol or tocopherol acetate (Column 4, lines

30-36) meeting claim 16 and the additive or antioxidant and or the wetting agents or surfactants or dispersing agents (column 4, line 66 to column 5 line 8) inherently meets the limitation of claims 16 and 17; the resinate is dispersed in Eudragit (column 7, lines 22-25) meeting the limitation of polyelectrolyte (claims 8 and 12); sucrose or fructose or sorbitol or lactose when present (column 4, lines 66, 67) meet claim 15; when gelatin or xanthan gum or guar gum (column 5, lines 4-7) meeting claims 6, 7, 11, 12; the mole/liter of counter ions present in the dispersion is a property of broad dosage forms that do not recite any specific amount of the ion-exchange resin so that the dosage from of the prior art inherently anticipates claim 13; the disclosure that the suspension is contemplated for oral administration (claim 12 and column 4, lines 55-57) meets the limitation of claim 21 since administration of any of the disclosed drugs would provide the effect of the drug that is obtainable from the drug. In particular, the amended claim 21 recites the drugs as "a cardiovascular drug, respiratory drug, sympathomimetic drug, cholinomemetic drug, adrenergic drug, antimuscarinic drug, antispasmodic drug, skeletal muscle relaxant, diuretic drug, anti-migraine drug, anesthetic, sedative, hypnotic, antiepileptic, psychopharmacologic agent, analgesic, including opioid and non-opioid analgesic, antipyretic, CNS stimulant, antineoplastic, immunosuppressive drug, antimicrobial drug, antihistamine, anti-inflammatory, antibiotic, decongestant, cough suppressant, expectorant or a combination thereof." Nonomura specifically discloses the following drugs meeting amended claim 21 in column 2, line 55 to column 3, and line 27, namely:

> "Drugs for the respiratory tract:
>
> Antitussive expectorants such as dihydrocodeine phosphate, codeine phosphate, noscapine hydrochloride, phenylpropanolamine hydrochloride, potassium guaiacolsulfonate, cloperastine fendizoate, dextromethorphan hydrobromide and chloperastine hydrochloride;

bronchodilators such as dl-methylephedrine hydrochloride and dl-methylephedrine saccharinate; and antihistamines such as dl-chlorpheniramine maleate.

Drugs for the digestive tract:

Digestive tract antispasmodics such as scopolamine hydrobromide, metixene hydrochloride and dicyclomine hydrochloride.

Drugs for the central nervous system:

Antipsychotic drugs such as phenothiazine derivatives (chlorpromazine hydrochloride, etc.) and phenothiazine-like compounds (chlorprothixene hydrochloride, etc.); antianxiety drugs such as benzodiazepine derivatives (chlordiazepoxide hydrochloride, etc.); antidepressants such as imipramine compounds (imipramine hydrochloride, etc.); antipyretic analgesics such as sodium salicylate; and hypnotics such as phenobarbital sodium.

Drugs for the respiratory system:

Coronary dilators such as etafenone hydrochloride; antiarrhythmics such as procainamide hydrochloride; Ca antagonists such as verapamil hydrochloride; hypotensive drugs such as hydrazine hydrochloride, propranolol hydrochloride and clonidine hydrochloride; and peripheral vasodiaators/vasoconstrictors such as tolazoline hydrochloride.

Antibiotics:

Macrolides such as oleandomycin phosphate; tetracyclines such as tetracycline hydrochloride; streptomycins such as fradiomycin sulfate; and penicillin drugs such as dicloxacillin sodium, pivmecillinam hydrochloride and carbenicillinindanyl sodium.

Chemotherapeutic drugs:

Sulfa drugs such as sulfisomidine sodium; antituberculosis drugs such as kanamycin sulfate; and antiprotozoan drugs such as amodiaquine hydrochloride.

In particular, an excellent sustained releasing effect is obtained in basic drugs for the respiratory tract such as dihydrocodeine phosphate, dl-methyl-ephedrine hydrochloride and phenylpropanolamine hydrochloride."

Response to Arguments

10. Applicant's arguments filed 8/22/2007 have been fully considered but they are not persuasive.

Applicant argues that Nonomura fails to disclose "a liquid form controlled release drug composition that includes ... an electrolytic drug associated with an ion exchange resin and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug."

Response:

In column 7, lines 22-25, Nonomura disperses the resinate in solution of EUDRAGIT, which is one of the polyelectrolytes recited in claim 8 and thus meets the requirement that the polyelectrolyte be of same charge as the electrolytic drug. Nonomura contemplates composition that is oral suspension (column 4, lines 55-62) meeting the requirements for liquid formulation. Therefore, contrary to applicant's conclusion, Nonomura discloses a liquid formulation that is a controlled release drug composition comprising an electrolytic drug associated with an ion exchange resin (abstract; column 3, lines 10-31; column 5, line 20) and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte (column 7, lines 22-25) having the same charge as the electrolytic drug.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-17 and 21 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application Nos. 11/150,937 (US 2006/0018972) and 11/198,937 (US 2006/0134148) in view of WO 95/19184. The copending claims differ from the examined claims in that the co-pending claims do not specify what the dispersing medium is comprised of. However, the Eudragit polymers are known as dispersing according to Cohen in WO 95/19184 (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Eudragit polymers as the dispersing polyelectrolyte in the dosage form of the examined claims.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

13. Applicant's remarks filed 8/22/2007 have been fully considered but they are not persuasive.

While applicant disagrees with the above provisional obviousness type double patenting rejection, applicant is requesting that the rejection be held in abeyance because the

rejection involves "pending application rather than an issued patent," applicant further requests the withdrawal of the provisional obviousness type double patenting rejection in order to assert the rejection in the pending application.

Response:

The above is not found persuasive because the provisional obviousness type double patenting rejection is not the only rejection in the examined application and the rejection will continue to be made until the rejection is overcome as stated in MPEP 804 [R-5], I B, that "the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications." As noted above, the provisional obviousness double patenting rejection is not the only rejection remaining in this examined application. Thus rejection is maintained and is not held in abeyance.

No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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